

10-07-05

P.F.V.



Express Mail No.: ED 933 427 856 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Donald J. KYLE et al.

Confirmation No.: 8122

Application No.: 10/625,708

Group Art Unit: 1624

Filed: July 24, 2003

Examiner: Kahsay Habte

Title: THERAPEUTIC AGENTS USEFUL  
FOR TREATING PAIN

Attorney Docket No.: 6750-174-999  
(CAM No.: 305158-999172)

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.56 and 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. §§ 1.56 and 1.97 to inform the Patent and Trademark Office ("Office") of all references coming to the attention of each individual associated with the filing and prosecution of the above-identified application that are or may be related to patentability of the claimed invention, Attorneys for Applicants hereby invite the Examiner's attention to references **A01-A26**, **B01-B13** and **C01-C31**, which are listed on the accompanying Form PTO-1449 entitled "List of References Cited By Applicant."

Legible copies of references **B01-B13** and **C01-C31** are submitted herewith. Also submitted with each of Refs. **B11**, **B12** and **B13** is a computer/machine translation into English and English abstracts of said references obtained from the Japanese Patent Office website and from Derwent.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of references **A01-A26**, being United States patents and published applications, are not submitted herewith but will be submitted if requested by the Office. Applicants note that Reference **A25** is an English language counterpart to International Publication No. WO 02/006234, and Reference **A26** is an English language counterpart to International Publication No. WO 02/074743.

No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made. 37 C.F.R. §§1.97(g) and (h).

Applicants request that the Examiner review all the references identified on the attached Form PTO-1449, and that they be made of record in the file history of the above-identified application.

As this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits, Applicants estimate that no fee is required. Should a fee be required, the Commissioner is authorized to charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

*Samuel B. Abrams by*  
*George A. Suiel 43,140*

Date: October 5, 2005

Samuel B. Abrams

(Reg. No. 30,605)

**JONES DAY**

222 East 41st Street

New York, New York 10017

(212) 326-3939

Enclosures

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

 ATTY. DOCKET NO.  
 6750-174-999  
 (305158-999172)

 APPLICATION NO.  
 10/625,708

APPLICANT

Donald J. KYLE et al.

FILING DATE

July 24, 2003

GROUP

1624

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,439,606	03/27/1984	De et al.	544	356	
	A02	4,450,272	05/22/1984	Du et al.	544	357	
	A03	5,039,680	08/13/1991	Imperato et al.	514	304	
	A04	5,075,341	12/24/1991	Mendelson et al.	514	282	
	A05	5,198,459	03/30/1993	Imperato et al.	514	397	
	A06	5,232,934	08/03/1993	Downs	514	345	
	A07	5,430,033	06/04/1995	Cliffe et al.	514	254	
	A08	5,442,064	08/15/1995	Pieper et al.	544	360	
	A09	5,461,047	10/24/1995	Hansen Jr. et al.	514	211	
	A10	5,556,837	09/17/1996	Nestler et al.	514	21	
	A11	5,556,838	09/17/1996	Mayer et al.	514	25	
	A12	5,574,052	11/12/1996	Rose et al.	514	343	
	A13	5,607,936	05/04/1997	Chiang et al.	514	255	
	A14	5,756,504	05/26/1998	Bock et al.	514	252	
	A15	5,762,925	06/09/1998	Sagen	424	93.7	
	A16	5,789,412	08/04/1998	Halazy et al.	514	255	
	A17	5,792,768	08/11/1998	Kulagowski et al.	514	255	
	A18	6,028,195	02/22/2000	Cho et al.	544	360	
	A19	6,109,269	08/29/2000	Rise et al.	128	898	
	A20	6,204,284	03/20/2001	Beer et al.	514	412	
	A21	6,329,395	12/11/2001	Dugar et al.	514	329	
	A22	2003/0153596	08/14/2003	Suh et al.	514	311	
	A23	2003/0158188	08/21/2003	Lee et al.	514	228.2	
	A24	2003/0158198	08/21/2003	Lee et al.	514	241	
	A25	2003/0187023	10/02/2003	Kubo et al.	514	318	
	A26	2004/0106622	06/03/2004	Morie et al.	514	252.14	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	WO 96/21648	07/18/1996	PCT				
	B02	WO 98/00402	01/08/1998	PCT				
	B03	WO 99/07672	02/18/1999	PCT				
	B04	WO 00/52001	09/08/2000	PCT				
	B05	WO 02/05819	01/24/2002	PCT				

	B06	WO 02/16318	02/28/2002	PCT				
	B07	WO 03/022809	03/20/2003	PCT				
	B08	WO 03/062209	07/31/2003	PCT				
	B09	WO 03/068749	08/21/2003	PCT				
	B10	EP 1 122 242 A1	0808/2001	EP				
	B11	JP 10-007572	01/13/1998	Japan			XXX	
	B12	JP 2001-328938	11/27/2001	Japan			XXX	
	B13	JP 2001-261657	09/26/2001	Japan			XXX	

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

	C01	Berkow et al., The Merck Manual of Medical Information 1997; 345-350
	C02	Berkow et al., The Merck Manual of Medical Information 1997; 352-355
	C03	Berkow et al., The Merck Manual of Medical Information 1997; 496-500
	C04	Berkow et al., The Merck Manual of Medical Information 1997; 525-526
	C05	Berkow et al., The Merck Manual of Medical Information 1997; 528-530
	C06	Berkow et al., The Merck Manual of Medical Information 1997; 530-532
	C07	Berkow et al., The Merck Manual of Medical Information 1997; 631-634
	C08	Chiamulera et al., "Reinforcing and Locomotor Stimulant Effects of Cocaine are Absent in mGluR5 Null Mutant Mice," Nat Neurosci 2001; 4(9):873-874
	C09	Cooke, "Glycopyrrolate in Bladder Dysfunction," S Afr Med J 1983; 63:3
	C10	Di Marzo et al., "Endovanilloid Signaling in Pain," Curr Opin Neurobiol 2002; 12:372-379
	C11	Dogrul et al., Peripheral and Spinal Antihyperalgesic Activity of SIB-1757, a Metabotropic Glutamate Receptor (mGluR <sub>5</sub> ) Antagonist, In Experimental Neuropathic Pain in Rats," Neurosci Lett 2000; 292(2):115-118
	C12	Foley, "Pain" Cecil Textbook of Medicine 1996; 100-107
	C13	Fundytus et al., "Antisense Oligonucleotide Knockdown of mGluR <sub>1</sub> Alleviates Hyperalgesia and Allodynia Associated with Chronic Inflammation," Pharmacol Biochem Behav 2002; 73:401-410
	C14	Fundytus et al., "In Vivo Antinociceptive Activity of Anti-rat mGluR <sub>1</sub> and mGluR <sub>5</sub> Antibodies in Rats," NeuroReport 1998; 9:731-735
	C15	Fundytus et al., "Knockdown of Spinal Metabotropic Glutamate Receptor 1 (mGluR <sub>1</sub> ) Alleviates Pain and Restores Opioid Efficacy After Nerve Injury in Rats," Br J Pharmacol 2001; 132:354-367
	C16	Fundytus, "Glutamate Receptors and Nociception Implications for the Drug-Treatment of Pain," CNS Drugs 2001; 15:29-58
	C17	Goodman and Gillman's The Pharmaceutical Basis of Therapeutics 506, 901-915 (J. Hardman and L. Limbird eds., 9 <sup>th</sup> ed. 1996)
	C18	Herzog et al., "Urinary Incontinence: Medical and Psychosocial Aspects," Annu Rev Gerontol Geriatr 1989; 9:74-119
	C19	Kwak et al., "A Capsaicin-Receptor Antagonist, Capsazepine Reduces Inflammation-Induced Hyperalgesic Responses in the Rat: Evidence for an Endogenous Capsaicin-Like Substance," Neuroscience 1998; 84:619-626
	C20	Levin et al., "Direct Measurement of the Anticholinergic Activity of a Series of Pharmacological Compounds on the Canine and Rabbit Urinary Bladder," J Urol 1982; 128:396-398
	C21	Mirakhur et al., "Glycopyrrolate: Pharmacology and Clinical Use," Anaesthesia 1983; 38:1195-1204
	C22	Ohkubo et al., "The Selective Capsaicin Antagonist Capsazepine Abolishes the Antinociceptive Action of Eugenol and Guaiacol," J. Dent Res Apr 1997; 76(4):848-851
	C23	Ossowska et al., "Blockade of the Metabotropic Glutamate Receptor Subtype 5 (mGluR <sub>5</sub> ) Produces Antiparkinsonian-like Effects in Rats," Neuropharmacology 2001; 41:413-420
	C24	Pan et al., "Soluble Polymer-Supported Synthesis of Arylpiperazines," Tet Lett 1998; 39:9505-9508
	C25	Resnick, "Urinary Incontinence," Lancet 1995; 346:94-99
	C26	Spooren et al., "Novel Allosteric Antagonists Shed Light on mGluR <sub>5</sub> Receptors and CNS Disorders," Trends Pharmacol Sci 2001; 22(7):331-337
	C27	Tatarczyska et al., "Potential Anxiolytic- and Antidepressant-like Effects of MPEP, a Potent, Selective and Systemically Active mGluR <sub>5</sub> Receptor Antagonist," Br J Pharmacol 2001; 132(7):1423-1430
	C28	Urban et al., "In Vivo Pharmacology of SDZ 249-665, A Novel, Non-pungent Capsaicin Analogue," Pain 2000; 89:65-74

	C29	Walker et al., "Metabotropic Glutamate Receptor Subtype 5 (mGlu5) and Nociceptive Function. I. Selective Blockade of mGlu5 Receptors in Models of Acute, Persistent and Chronic Pain," Neuropharmacology 2000 40:1-9
	C30	Wein, "Pharmacology of Incontinence," Urol Clin North Am 1995; 22(3):557-577
	C31	Wu et al., "Multiple Sensory and Functional Effects of Non-phenolic Aminodimethylene Nonivamide: An Approach to Capsaicin Antagonist," Gen Pharmac 1996; 27(1):151-158

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	